IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC., and ALCON MANUFACTURING, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-234 (SLR)
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

ANSWER AND DEFENSES OF
DEFENDANT TEVA PHARMACEUTICALS USA, INC.

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), by and through its attorneys, hereby answers the Complaint in this action as follows:

1. Teva USA admits this is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Teva USA with the U.S. Food and Drug Administration, Teva USA's Abbreviated New Drug Application ("ANDA") No. 78-073 for "Moxifloxacin Hydrochloride Ophthalmic Solution" to obtain approval to engage in the commercial manufacture, use or sale of the drug product before the expiration of U.S. Patents 4,990,517, 5,607,942 and 6,716,830, and their pediatric exclusivities. Teva USA denies the remaining allegations of paragraph 1 of the Complaint.

2. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, and therefore denies them.

3. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, and therefore denies them.

4. Teva USA is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 4 of the Complaint, and therefore denies them.

5. Admitted.

6. Admitted.

7. Admitted for the purpose of this action only.

8. Teva USA incorporates its Answer to each of the preceding Paragraphs 1-7 as if fully set forth herein.

9. Teva USA admits that United States Patent No. 4,990,517 ("the '517 patent") issued on February 5, 1991 and that the '517 patent bears the title "7-(1-Pyrrolidinyl)-3-Quinolone- And -Naphthyridonecarboxylic Acid Derivatives As Antibacterial Agents And Feed Additives." Teva USA is without sufficient information as to the truth of the allegation regarding the assignment of the '517 patent, and Teva USA denies the remaining allegations in paragraph 9 of the Complaint.

10. Teva USA admits that United States Patent No. 5,607,942 ("the '942 patent") issued on March 4, 1997 and that the '942 patent bears the title "7-(1-Pyrrolidinyl)-3-Quinolone-And -Naphthyridone-Carboxylic Acid Derivatives As Antibacterial Agents And Feed Additives." Teva USA is without sufficient information as to the truth of the allegation regarding the assignment of the '942 patent, and Teva USA denies the remaining allegations in paragraph 10 of the Complaint.

11. Teva USA is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in paragraph 11 of the Complaint, and therefore denies them.

12. Teva USA is without sufficient information to form a belief as to the truth of the allegation that Plaintiff Bayer HealthCare AG ("BHC") owns both the '517 patent and the '942 patent, and Teva USA denies the remaining allegations in paragraph 12 of the Complaint.

13. Teva USA admits that it sent a letter dated February 21, 2006 to Bayer Healthcare, Pharmaceutical Division, Bayer HealthCare AG, Alcon Pharmaceuticals, Ltd., and Alcon Laboratories, Inc. to notify each of them that Teva USA had submitted its ANDA for Moxifloxacin Hydrochloride Ophthalmic Solution, and to inform them that Teva USA sought to obtain approval of its drug product prior to the expiration of the '517 patent, the '942 patent, the '830 patent, and their pediatric exclusivities. Teva USA denies the remaining allegations of paragraph 13 of the Complaint.

14. Teva USA denies each and every allegation in paragraph 14 of the Complaint.

15. Teva USA admits that it notified Bayer HealthCare AG, Bayer Healthcare, Pharmaceutical Division, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. Teva USA denies the allegations of paragraph 16 of the Complaint as stated but admits that its submission of ANDA No. 78-073 creates a cause of action for infringement in the patent holders of the '517, '942 and '830 patents.

17. Teva USA denies each and every allegation in paragraph 17 of the Complaint.

18. Teva USA denies each and every allegation in paragraph 18 of the Complaint.

19. Teva USA incorporates its Answers to each of paragraphs 1-7 of the Complaint as if fully set forth herein.

20. Teva USA admits that United States Patent No. 6,716,830 ("the '830 patent") issued on April 6, 2004 and that the '830 patent bears the title "Ophthalmic Antibiotic Compositions Containing Moxifloxacin." Teva USA is without sufficient information as to the

truth of the allegations regarding the assignment of the '830 patent and Teva USA denies the remaining allegations in paragraph 20 of the Complaint.

21. Teva USA is without sufficient information as to the truth of the allegation that Alcon, Inc. owns the '830 patent. Teva USA admits that Alcon, Inc. appears to hold an approved New Drug Application for VIGAMOX®. Teva USA denies the remaining allegations in paragraph 21 of the Complaint.

22. Teva USA is without sufficient information as to the truth of the allegation that Alcon Manufacturing, Ltd. has been granted an exclusive license under the '830 patent. Teva USA denies the remaining allegations in paragraph 22 of the Complaint.

23. Teva USA admits that it sent a letter dated February 21, 2006 to Bayer Healthcare, Pharmaceutical Division, Bayer HealthCare AG, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. to notify each of them that Teva USA had submitted its ANDA for Moxifloxacin Hydrochloride Ophthalmic Solution, and to inform them that Teva USA sought to obtain approval of its drug product prior to the expiration of the '517 patent, the '942 patent and the '830 patent, and their pediatric exclusivities. Teva USA denies the remaining allegations of paragraph 23 of the Complaint.

24. Teva USA denies each and every allegation in paragraph 24 of the Complaint.

25. Teva USA admits that it notified Bayer HealthCare AG, Bayer Healthcare, Pharmaceutical Division, Alcon Pharmaceuticals Ltd., and Alcon Laboratories, Inc. that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

26. Teva USA denies each and every allegation in paragraph 26 of the Complaint.

27. Teva USA denies the allegations of paragraph 27 of the Complaint as stated but admits that its submission of ANDA No. 78-073 creates a cause of action for infringement in the patent holders of the '517, '942 and '830 patents.

28. Teva USA denies each and every allegation in paragraph 28 of the Complaint.

FIRST DEFENSE

29. The drug product for which Teva USA has filed its Abbreviated New Drug Application (ANDA) will not infringe any valid claim of any of the '517, '942, or '830 patents.

SECOND DEFENSE

30. The '517 patent and each of the claims allegedly infringed by Teva USA are invalid for failure to comply with one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103, and/or 112.

31. The '942 patent and each of the claims allegedly infringed by Teva USA are invalid for failure to comply with one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103, and/or 112.

32. The '830 patent and each of the claims allegedly infringed by Teva USA are invalid for failure to comply with one or more of the conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103, and/or 112.

33. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Teva USA's ANDA included a certification with respect to the '517, '920 and '830 patents. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iii) and (iv), Teva USA also provided each of Bayer Healthcare, Pharmaceutical Division, Bayer HealthCare AG, Alcon, Inc., and Alcon Manufacturing Ltd. ("Plaintiffs") with a detailed statement of the factual and legal basis of Teva USA's opinion regarding the invalidity, unenforceability or noninfringement of the claims of the '517, '942, and '830 patents.

34. Pursuant to 21 U.S.C. § 355 (j)(5)(C)(i)(III) Teva USA made an offer of Confidential Access to Plaintiffs of Teva USA's ANDA for the purpose of allowing Plaintiffs to determine whether to bring an action against Teva USA. Plaintiffs ignored Teva USA's offer and filed suit without availing themselves of the opportunity to fully investigate Teva USA's ANDA prior to filing suit.

35. Given Teva USA's detailed statement and the information and materials that Teva USA offered to provide to Plaintiffs, no reasonable litigant could expect success on the merits of this patent infringement action against Teva USA.

WHEREFORE, Teva USA requests entry of a judgment:

A. Dismissing Plaintiffs' Complaint with prejudice;

B. Denying all relief requested by Plaintiffs and any relief to Plaintiffs whatsoever;

C. That Teva USA has not infringed and is not infringing any valid and enforceable claim of the '517, '942, or '830 Patents;

D. Awarding Teva USA reasonable attorney's fees pursuant to, *inter alia*, 35 U.S.C. § 285;

E. Awarding Teva USA its costs of this action; and

F. Awarding Teva USA such additional relief as this Court Deems just and proper.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

Bruce M. Gagala
M. Daniel Hefner
Brian A. Garcia
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601

Dated: April 28, 2006
730041 / 30271

By: */s/ Richard L. Horwitz*
Richard A. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza, 6th Floor
P.O. Box 951
Wilmington, Delaware 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendant,
TEVA PHARMACEUTICALS USA, INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on April 28, 2006, the attached document was hand-delivered to the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF:

Rudolf E. Hutz
Jeffrey B. Bove
Connolly Bove Lodge & Hutz LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899-2207

I hereby certify that on April 28, 2006, I have Electronically Mailed the documents to the following non-registered participants:

Bruce R. Genderson
Adam L. Perlman
Aaron P. Maurer
David I. Berl
Dov P. Grossman
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005
bgenderson@wc.com
aperlman@wc.com
amaurer@wc.com
dberl@wc.com
dgrossman@wc.com

By: */s/ Richard L. Horwitz*
Richard L. Horwitz
David E. Moore
Potter Anderson & Corroon LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19899-0951
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

730055